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Friedrich Magerl

MAGERL2

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EXAMINER

BRUTUS, JOEL F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,761	Applicant(s) MAGERL ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: The independent claim doesn't include a preamble. Appropriate correction is required.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract of record is a copy of the front page of PCT application. A new abstract is required.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Regarding claim 3, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

5. Regarding claims 1-2, 9 the phrase "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Appropriate correction is required.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, the word "optionally" renders the claim indefinite; it is not clear when one or the other will be picked.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2, 9-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanof et al (US Pat: 6,064,904) stand alone.

Regarding claim 1, Yanof et al teaches a patient table or support that includes a patient supporting surface that is mounted for longitudinal movement relative to a base portion that includes a motor for raising and lowering the patient support surface and for moving the patient support surface longitudinally that is pertinent to the claimed invention. Position encoders are also provided for generating electrical signals indicative of the height and longitudinal position of the patient support [see fig 1 and column 3 lines 47-53]. In fig the table (denoted 10) is moveable or displaceable in longitudinal direction and a sliding way [see fig 1]. The table slides in and out a bore (denoted 20). The bore is in fact a gantry to receive the CT table and patient support (emphasis added).

Yanof et al further teaches a planning, preferably a volumetric diagnostic imaging apparatus is disposed in axial alignment with the patient table such that a patient or subject on the patient support surface can be moved into and through a bore of the volumetric imager. In the illustrated embodiment, the volumetric imager is a CT scanner which includes an X-ray tube mounted for repeated circular travel within a preselected plane [see column 3 lines 61-67]. Yanof also teaches a mechanical arm assembly (is being used as a retainer to hold an instrument) which is supported from overhead by a carriage movable on an oval track system affixed to the top of the volumetric diagnostic imaging apparatus to hold a surgical minimally invasive instrument carried on an interchangeable surgical instrument guidance device [see column 4 lines 25-43].

Yanof et al teaches in figure 2 that the mechanical arm which is used as a retainer; the arm as shown generally in FIG. 2 and includes a plurality of arm segments which are interconnected by pivot members forming joints between the arm segments. In that way, a free end of the arm is selectively movable in multiple orientations as necessary to position the surgical instrument (FIG. 1) into various desired positions over the patient support. A base member is rigidly connected to the carriage using suitable fasteners, epoxies, or the like [see column 4 lines 45-53]. The carriage is lockable in one or more predetermined fixed locations on the track [see column 4 lines 28-31] so this feature can fix the unit in fixed position (emphasis added).

Yanof et al teaches during the planning stage of a medical procedure, the patient is positioned in the volumetric planning scanner and a volumetric image is generated. The volumetric image is stored in a volumetric or planning data memory. The position of the patient table during the generation of the planning data, particularly as the table moves to generate spiral or slice data, is stored in conjunction with the volumetric planning data such that the data is correlated with the patient table coordinate system. The operator control controls the volume planning image data memory and a video processor such that selected slices, projection images, surface renderings, or other conventional displays of the data are generated for display on a planning image display. Preferably, the planning image display includes a pair of transverse axial slices through the patient and a pair of oblique axial and sagittal slices through common points of intersection along a virtual needle line [see column 6 lines 42-54].

Yanof et al teaches each of the views displayed are simultaneously updated to reflect the then current position and orientation of a surgical planning device on a stereotactic mechanical arm assembly [see abstract].

Yanof et al doesn't teach a retainer.

However, Yanof et al teaches in figure 2 that the mechanical arm which is used as a retainer; the arm as shown generally in FIG. 2 and includes a plurality of arm segments which are interconnected by pivot members forming joints between the arm segments. In that way, a free end of the arm is selectively movable in multiple orientations as necessary to position the surgical instrument (FIG. 1) into various desired positions over the patient support.

Therefore, it would have been obvious to one with ordinary skill in the art to modify the Yanof et al teaching by using the mechanical arm as a retainer to hold and guide an instrument as taught by Yanof et al; for the purpose navigate medical instrument with great accuracy and higher precision.

Regarding claims 2 and 10, Yanof et al teaches a patient support that is displaceable in the manner of a slide on the base plate (base portion as taught by Yanof et al [see fig 1]. Yanof et al teaches in fig 1 the support is arranged in a way that it can be fixed on the base portion as shown in fig 1.

Regarding claim 9, all other limitations are taught as set forth by the above teaching.

Yanof et al doesn't teach deliver a laser beam.

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However, Yanof et al discloses that when a laser planning instrument is used, the point where linear trajectory defined by the surgical planning device intersects the patient's body defines the patient entry point. Alternatively, when a cannula is used, the patient entry point becomes the point where the cannula touches the patient's skin. The patient entry point is illustrated on the first transverse axial view as a small highlighted circle.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to mark a point to deliver laser into the patient; in order to accurately irradiate the region of interest and to avoid the possibility of hitting surround healthy areas.

Regarding claim 11, all other limitations are taught as set forth by the above teaching.

Yanof et al doesn't specifically disclose that the base portion is made of X-ray translucent material.

However, Yanof et al discloses that The X-ray tube projects a fan-shaped beam of radiation through a ring of radiation translucent material, through the patient support, through a region of interest of the subject, and to a ring or arc of radiation detectors positioned opposite the X-ray tube [see column 4 lines 1-10].

Therefore, it is obvious that the base portion as taught by Yanof et al must be made of X-ray translucent material since the patient support and the base portion

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constitute one unit [see fig 1]. One with ordinary skill would have been motivated to use a base portion or plate that is X-ray compatible; in order to minimize cross talks.

Regarding claims 12-13, all other limitations are taught as set forth by the above teaching.

Yanof et al doesn't teach belts to stretch across the patient's body and base plate is secured to the table by belts.

However, Yanof et al teaches a base member is rigidly connected to the carriage using suitable fasteners, epoxies, or the like [see column 4 lines 45-53].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to use fasteners to tie the patient to the support table and fastener to secure the base to the CT table; in order to minimize patient's movement and to stabilize the patient support and to control the sliding movement into the bore (gantry).

Regarding claim 15, all other limitations are taught as set forth by the above teaching. The above teaching is pertinent to the method steps as claimed. Yanof et al teaches during the planning stage of a medical procedure, the patient is positioned in the volumetric planning scanner and a volumetric image is generated. The volumetric image is stored in a volumetric or planning data memory. The position of the patient table during the generation of the planning data, particularly as the table moves to generate spiral or slice data, is stored in conjunction with the volumetric planning data

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such that the data is correlated with the patient table coordinate system. The operator control controls the volume planning image data memory and a video processor such that selected slices, projection images, surface renderings, or other conventional displays of the data are generated for display on a planning image display. Preferably, the planning image display includes a pair of transverse axial slices through the patient and a pair of oblique axial and sagittal slices through common points of intersection along a virtual needle line [see column 6 lines 42-54]. Yanof et al

The above teaching is silent to adjusting the gantry to the level of the work plane.

However, Yanof et al teaches adjusting the patient support which is the work plane in the planning phase to maintain registration; gantry (z-axis) and patient support height [see column 6 lines 20-31].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to adjust the gantry; in order to efficiently and accurately perform the procedure.

9. Claims 3-8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanof et al (US Pat: 6,064,904) in view of Mun et al (Pub. No.: US 2002/0196906)

Regarding claims 3-6, all other limitations are taught as set forth by the above teaching.

The above teaching is silent to a cylinder and inserting a drill, pins or screws.

However, Yanof et al teaches in fig 1 and 2 a base member (denoted 42) and a mechanical arm (retainer) that comprises a needle knob and a instrument guidance to

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receive and guide a surgical instrument (which could be a drill, pins or screws, emphasis added). Fig 2 shows that the member has joints to receive the mechanical arm and these joints allow rotation of the arm. Yanof et al teaches position encoders to monitor the longitudinal position and rotational position [see column 4 lines 10-25]. And encoders to The optical incremental encoders generate feedback pulses indicative of the relative angular and rotational position of the various arm members with respect to each other in a well known manner [see column 5 lines 1-5].

However, Mun et al teach platform straddles the surgical site and is secured to the patient via small screws, posts, clamps or pads. The attachment points are optionally permanently mounted on the reference platform or are selectively detachable. Optionally, irregularities are incorporated into the surfaces or edges of the reference frame to form the basis of position and unique identification information as is determined by medical imaging equipment [see 0028].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using screws, clamps as taught by Mun et al; for the purpose of guiding and implant a surgical tool.

Regarding claims 7 and 8, all other limitations are taught as set forth by the above teaching.

The above teaching is silent to the cylinder made of metal and radioparent material

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However, Mun et al teaches an alignment device allows a physician to measure an angle subtended between a medical instrument and a reference platform or an OR table. A reference platform is temporarily secured to a surgical patient. The reference platform is constructed of an x-ray and/or magnetic resonance compatible, temporary structural material illustratively including plastics such as TEFLON and HDPE; low Z metals such as aluminum; and cartilaginous materials [see 0028].

Therefore, one with ordinary skill the art at the time the invention was made would have been motivated to combine these references by using a platform made of x-ray and/or magnetic compatible such as Teflon, HDPE, low Z metal etc... as taught by Mun et al; for the purpose having high resolution.

Regarding claim 14, all other limitations are taught as set forth by the above teaching.

Yanof et al doesn't teach the support comprises an arc shaped rail.

However, Mun et al also discloses in fig 1 that the table is slidable, displaceable using the retractable rollers as shown by the arrow in fig 11.

Therefore, one with ordinary skill the art at the time the invention was made would have been motivated to combine these references by using retractable rollers as taught by Mun et al; for the purpose smoothly displace the support in and out of the gantry.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768